**NIH POLICY MANUAL**

# 3056 - REQUESTS FOR WAIVER OF THE U.S. MANUFACTURING REQUIREMENT IN LICENSES TO EXTRAMURAL INVENTIONS

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**Release Date: 10/07/96**

1. **Explanation of Material Transmitted:** This chapter is being issued to describe the procedures for proper review and disposition of requests for waiver of the U.S. manufacture requirement that is included in license agreements for extramural inventions.

2. **Filing Instructions:**

   **Remove:** NONE
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## A. Purpose:

This Manual Chapter establishes procedures for proper review and disposition of requests for waiver of the U.S. manufacture requirement that is included in license agreements for extramural inventions. All previous procedures are superseded.

## B. Background:

The primary mission of the Public Health Service (PHS) is to improve human health by increasing scientific knowledge related to health and disease through the conduct and support of biomedical and behavioral research. In 1994, the NIH was delegated by

the PHS Assistant Secretary for Health responsibility as lead agency for PHS technology transfer activities. In support of the PHS technology transfer program, the NIH Office of Technology Transfer was delegated by the Director, NIH, the authority to waive the preference for United States industry requirement when a contractor assigns or licenses a contractor owned invention (35 U.S.C. 204). Extramural institutions generally will request such a waiver on behalf of its licensees. The following procedures are to be followed in processing and responding to such requests for waivers of the U.S. manufacturing requirement.

The National Institutes of Health and the Food and Drug Administration are referenced as PHS agencies within the Department of Health Service within the Department of Health and Human Services.

**C. Policy:**

The National Institutes of Health shall comply with 35 U.S.C 204 in making determinations regarding the grant of a waiver of the U.S. manufacturing requirement. Section 204 states:

> Notwithstanding any other provision of this chapter, no small business or firm or nonprofit organization which receives title to any subject invention and no assignee of any such small business firm or nonprofit organization shall grant to any person the exclusive right to use or sell any subject invention in the United States unless such person agrees that any products embodying the subject invention or produced through the use of such invention will be manufactured substantially in the United States. However, in individual cases, the requirement for such an agreement may be waived by the Federal agency under whose funding agreement the invention was made upon a showing by the small business firm, nonprofit organization, or assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible.

Waivers may be granted under this provision upon a determination by OTT that either 1) reasonable but unsuccessful efforts have been made to license the invention; or 2) that under the circumstances, domestic manufacture is not commercially feasible.

**D. Reference:**

This policy also can be found in the U.S. Public Health Service Technology Transfer Manual as Chapter 604.

**E. Definitions:**

1. Extramural Institution - any institution, commercial or academic, that is not another Federal agency.

2. Invention - any invention or discovery which is or may be patentable or otherwise protectable under Title 35 of the United States Code, or any novel

variety of plant which is or may be protectable under the Plant Variety Protection Act (7 U.S.C. 2321 et seq.).

3. Request for Waiver - request for exemption of the U.S. manufacture requirement that is included in license agreements for extramural inventions.

4. Subject Invention - any invention of a contractor conceived or first actually reduced to practice in the performance of work under a funding agreement.

5. Technology - scientific method or material used to achieve industrial or commercial objectives.

**F. Procedures:**

1. The extramural institution shall submit a request for a waiver of the U.S. manufacturing requirement to the NIH Office of Extramural Research (OER).

2. The OER shall send a copy of the request to the OTT and to the Technology Development Coordinator (TDC) of the appropriate Institute, Center or Division (ICD).

3. The OTT shall docket the written request upon receipt (appropriate date entered into the Invention Tracking System and a "G" number is assigned) and shall assign the request to the appropriate Branch within the Division of Technology Development and Transfer, OTT.

4. The request shall be assigned by the Branch Chief to a Licensing Specialist for evaluation of the request and recommendation to the Director or Deputy Director, OTT.

5. Factors to be considered by the Licensing Specialist in making a recommendation waiver include:

a. Reasonable but Unsuccessful Efforts to License:

(1) The significance of the technology, the availability of alternative products, size of intended patient populations, whether requiring U.S. manufacture will delay entry of the product into the U.S. or foreign markets, and the effect such delay may have on the U.S. and foreign public health.

(2) Past marketing strategy and efforts for the technology, including i) number of companies contacted; ii) methods used for marketing and contacting companies; iii) types of licenses and terms offered to potential licensees; iv) comparison of terms offered to potential foreign licensee and those offered to U.S. companies; and v) responses of companies to marketing efforts.

b. Not Commercially Feasible:

(1) The state of the worldwide market for the potential product, including what companies, if any, make the same or similar products and where such products are

manufactured, whether requiring U.S. manufacture will delay entry of the product into the U.S. or foreign markets, and the effect such delay may have on the U.S. and foreign public health.

(2) The part or percentage of products arising from the invention that would be manufactured outside the U.S.;

(3) The applicant's manufacturing capabilities within the U.S. and the efforts made by the applicant to locate, develop, or contract for such manufacturing capabilities;

(4) The circumstances that make foreign manufacture necessary;

(5) The factors making domestic manufacture not commercially feasible, including the relative costs of U.S. and foreign manufacturing;

(6) The importance of the technology to the public health, including a discussion of alternative products or therapies available and the size of the intended patient population;

(7) The value or benefit to the United States of licensing the technology even if it will not be manufactured in the United States, including i) the direct or indirect investment in U.S. plants or equipment, ii) the creation of new or higher quality U.S.-based jobs, iii) the enhancement of the domestic skills base, iv) the further domestic development of the technology, v) a positive impact on the U.S. trade balance considering product and service exports as well as foreign licensing royalties and receipts, vi) cross-licensing, sublicensing, and reassignment provisions in the license which seek to maximize benefits to the U.S., and vii) balance between the use of government resources in furtherance of agency program goals.

(8) The Licensing Specialist prepares a memorandum to the OTT Deputy Director (with a copy to the appropriate TDC) discussing the above factors and making a recommendation as to the determination to be made. A copy of any forms provided by the OER is attached for signature by the OTT Deputy Director.

(9) The OTT Deputy Director signs the memorandum indicating whether he or she concurs or does not concur with the recommendation and signs any forms provided by the OER as appropriate to implement the OTT determination. The memo and forms are then returned to the Licensing Specialist.

(10) The Licensing Specialist makes a copy of the signed memorandum and forms for the OTT files and forwards the originals to the OER, which will notify the extramural institution of the decision. Additionally, the Licensing Specialist updates the Invention Tracking System as appropriate to indicate the disposition of the request.

**G. Records Retention and Disposal:**

this Chapter, records pertaining to a requests for waivers of the U.S. manufacturing

uirement in licenses to extramural inventions are retained and disposed of under the hority of NIH Manual 1743 "Keeping and Destroying Records," Appendix 1, "NIH cords Control Schedule," Item 1100-L, Patents, Inventions and Licensing. Refer to nual for specific disposal instructions.

**Effective Date:**

policy and procedures set forth in this Manual Chapter are effective immediately.

**dditional Information:**

additional information on this Manual Chapter, contact Ms. Barbara McGarey, Deputy ector, Office of Technology Transfer, on (301) 496-7057.